Dockets Management Branch (HFA-305) Food and Drug Administration 5630 Fishers Lane, Room. 1061

Rockville, MD 20852

email: FDADockets@oc.fda.gov

Re: Notice of Participation of Kaiser Permanente in FDA Regulation of OTC Drug Products Hearing — Docket No. 00N-1256

To Whom It May Concern:

By this letter, Kaiser Permanente notices its request to participate in the Section 15 hearing on FDA regulation of OTC drug products on June 28 and 29. If at all possible, we would appreciate being scheduled for June 28.

I will be representing Kaiser Permanente at the hearing. The relevant details are:

Representative:

Anthony Barrueta, Counsel, Government Relations

Address:

One Kaiser Plaza

Oakland, California 94612

Telephone:

510-271-6835

Affiliation:

Kaiser Foundation Health Plan, Inc. and

The Permanente Medical Group, Inc.

Sponsor:

Kaiser Foundation Health Plan, Inc.

The presentation will deal primarily with marketplace and economic issues relating to Rx-to-OTC switches as they relate to prescription drug benefits and costs. It will include information collected by Kaiser Permanente's California Division about the frequency of adverse events experienced with less-sedating prescription antihistimines. It will suggest a role for health plans and PBMs in collecting data that can support the FDA's efforts in this area. It will suggest reference to international experiences in considering OTC switch citizen petitions. I expect the presentation to take no more than 8-10 minutes.

Please do not hesitate to contact me with any questions you may have.

Sincerely,

/s/

Anthony Barrueta Counsel



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Kaiser Foundation Health Plan, Inc.